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Application Number

10/664,837

Filing Date

September 17, 2003

RECEIVED

First Named Inventor

James T. Perkins, CENTRAL FAX CENTER

Art Unit

3763

JUL 13 2007

Examiner Name

LoAn H. Thanh

P03320 (6639-000051/US)

ENCLOSURES (check all that apply)

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 Fee Attached
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 Affidavits/declaration(s)
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Remarks

The Commissioner is hereby authorized to charge the amount of \$500.00 and any additional fees that may be required under 37 CFR 1.16 or 1.17 to Deposit Account No. 08-0750.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm

Harness, Dickey & Pierce, P.L.C.

Signature

Printed Name

Michael L. Smith

Date

July 13, 2007

Reg. No.

35,685

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July 13, 2007

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: James T. Perkins, et al.)	Examiner: LoAn H. Thanh
Serial No.: 10/664,837)	Group No.: 3763
Filed: September 17, 2003)	Docket No: P03320
Title: PHACOEMULSIFICATION NEEDLE)	(6639-000051/US)

**AMENDED APPEAL BRIEF
(37 C.F.R. § 41.37)**

Mail Stop Appeal Brief – Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313

Dear Sir:

Applicant appeals the Final Rejection in the above-identified application dated 17 January 2007, and submits this amended Appeal Brief in support. Appellant's Brief under 37 C.F.R. 1.192 is enclosed herewith. It is believed that no extensions of time are required. It is not believed that no additional fees are required, but if this is incorrect, the Commission is authorized to charge any additional amount to Deposit Account No. 08-0750.

I. REAL PARTY IN INTEREST

The real party in interest in the present case is Bausch & Lomb Incorporated.

II. RELATED APPEALS AND INTERFERENCES

There are no other related Appeals or Interferences known to Appellant.

III. STATUS OF CLAIMS

Currently pending claims 1, 2, 5, 6, 9, and 10 stand rejected under 35 U.S.C. §103 and are being appealed. Claims 5 and 6 were originally filed with the application, and claims 1, 2, 9, and 10 have previously been amended. Claims 3, 4, 7, 8, 11, and 12 have previously been cancelled.

IV. STATUS OF AMENDMENTS

No amendment was filed subsequent to the final rejection. This is because essentially the same arguments have previously been presented to the Examiner, and have not been accepted by the Examiner to date.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The present invention relates to a phacoemulsification cannula 10 including a threaded hub 18 for engagement with a phacoemulsification surgical instrument 30. An elongated phacoemulsification needle 12 has a proximal end 14 attached to the hub 18 and a distal end 16. The needle 12 has first and second inner diameters 22 and 24. The first inner diameter 22 is larger than the second inner diameter 24, and a transition 26 from the first inner diameter 22 to the second inner diameter 24 is closer to the proximal end 14 than to the distal end 16. See FIGs. 1 and 2 and the specification at pages 4-5.

Independent claim 1 claims a phaco cannula 10 having a threaded hub 18 for engagement with a phacoemulsification surgical instrument 30. An elongated phacoemulsification needle 12 has a proximal end 14 attached to the hub 18 and a distal end 16. The phacoemulsification needle 12 has first and second inner

diameters 22 and 24. The first inner diameter 22 is larger than the second inner diameter 24. A transition 26 from the first inner diameter 22 to the second inner diameter 24 is closer to the proximal end 14 than to the distal end 16 and the first inner diameter 22 extends from the distal end 16 toward the proximal end 14. Ultrasonic energy is transferred from the surgical instrument 30 to the needle 12 during surgery. Again see FIG. 2 and the specification at pages 4-5.

Independent claim 5 claims an elongated phacoemulsification needle 12 having proximal and distal ends 14 and 16. The proximal end 14 is structured for attachment to a phacoemulsification surgical instrument 30. The needle has first and second inner diameters 22 and 24; the first inner diameter 22 is larger than the second inner diameter 24 and a transition 26 from the first inner diameter 22 to the second inner diameter 24 is closer to the proximal end 14 than to the distal end 16. The first inner diameter 22 extends from the distal end 16 toward the proximal end 14. See FIG. 2 and the specification at pages 4-5.

Independent claim 9 claims phaco cannula 10 with an elongated phacoemulsification needle 12 having proximal and distal ends 14 and 16. The proximal end 14 is structured for attachment to a phacoemulsification surgical instrument 30. A first bore 22 within the cannula 10 extends from the distal end 16 toward the proximal end 14. A second bore 24 within the cannula 10 extends from the proximal end 14 to the first bore 22. The second bore 24 has a smaller diameter than the first bore 22 and is of sufficient length to provide a desired pressure drop during use across the length of the second bore 24. An

intersection of the first and second bores 22 and 24 is nearer the proximal end 14 than the distal end 16. See FIG. 2 and the specification at pages 4-6.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The ground of rejection being reviewed is that Claims 1, 2, 5, 6, 9, and 10 have been improperly rejected under 35 U.S.C. §103 as being unpatentable over Zadno-Azizi et al. (US Patent 5,997,562) in view of Eliasen et al. (US Patent 6,332,874).

VII. ARGUMENTS

35 USC § 103 REJECTION

The Examiner asserts that Zadno-Azizi et al. disclose a cannula having a hub, an elongated needle having first and second inner bores wherein the first bore is larger than the second and extends from the distal end toward the proximal end and wherein the transition region is closer to the proximal end than the distal end. The appellant agrees that Zadno-Azizi et al. show a sheath with a larger distal bore compared to the proximal bore and that the transition between the bores is closer to the proximal end than to the distal end. That is the extent of the similarity between the prior art and the present invention. The cited art does not come close to rendering obvious the present invention as claimed.

The Examiner has taken the position that since Zadno-Azizi discloses making the sheath out of various polymer materials that the sheath is per se capable of engagement with a phacoemulsification instrument and transferring ultrasonic energy. This statement is wholly unsupported. Since the cited prior art is not concerned with ultrasonic energy transmission and does not mention ultrasound anywhere in the patent, it is improper for the Examiner to assume the

sheath has such capabilities. Ultrasonic energy transmission causes significant stresses on the objects subjected to such energy. At col. 7 lines 49-65 there is described a slip-fit assembly of the sheath assembly's various parts. Ultrasonic energy flowing through such an assembly would shake it apart in short order. Col. 8 lines 44-45 does suggest that the assembly "may be molded into a single piece". It is unclear what this one sentence statement means because if the assembly were truly one piece then there would not be any strain relief tubing. But even if the assembly were one piece of polymer tubing it is not clear that ultrasonic energy could be effectively transmitted through such a sheath. Phacoemulsification cannulas are typically quite rigid and almost always made from metallic materials such as titanium so that the ultrasonic energy is efficiently transmitted through the cannula and so that the cannula can withstand the significant forces applied to it as it breaks up a cataract in a patient's eye. The need for strain relief in the Zadno-Azizi sheath also suggests that it would not be robust enough for phacoemulsification surgery. If the Zadno-Azizi sheath assembly requires strain-relief tubing then the sheath assembly is likely to buckle during use in phacoemulsification surgery. The Zadno-Azizi sheath is made to be inserted into a mating connector, not to withstand the significant stresses of cataract surgery.

The Examiner has used the Eliasen reference for the proposition of a threaded hub and combined it with Zadno-Azizi to reject the pending claims. The fact that Eliasen discloses a threaded hub is of little import. The Zadno-Azizi reference is what does not teach or suggest the claimed present invention.

By definition, an obviousness rejection is based on the fact that all limitations are not found within a single prior art reference. *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542 (Fed. Cir. 1983). The Examiner is permitted to combine prior art references or singly modify a prior art reference in order to construct an obviousness rejection.

Applicants challenge the use of the Zadno-Azizi and Eliasen references as irrelevant to the instant application. Additionally, applicants reject the combination of the Zadno-Azizi and Eliasen references based on a lack of motivation to combine the references.

The prior art cited by the Examiner is not within the field of endeavor of the applicant and has improperly been cited against the pending claims. The instant application is directed to phacoemulsification needles for ophthalmic surgery for breaking up and removing cataracts. The Zadno-Azizi reference is directed to a sheath for introducing wires or balloons on wires into a blood vessel. If the prior art is from a non-analogous field it is improper to use such art to reject the subject claims. See, *In re Watter*, 147 F.2d 685, 64 USPQ 571 (C.C.P.A. 1945). See also, *Wang Labs., Inc. v Toshiba Corp.*, 993 F.2d 858, 26 USPQ 2d 1767 (Fed. Cir. 1993).

The following quote from *In re Oetiker* is particularly relevant in the present case. The Federal Circuit stated

It has not been shown that a person of ordinary skill, seeking to solve a problem of fastening a hose clamp, would reasonably be expected or motivated to look to fasteners for garments. The combination of elements from non-analogous sources, in a manner that reconstructs the Applicant's invention only with the benefit of hindsight, is insufficient to present a

prima fascia case of obviousness. There must be some reason, suggestion, or motivation found in the prior art whereby a person of ordinary skill in the field of the invention would make the combination. That knowledge cannot come from the Applicant's invention itself . . . Oetiker's invention is simple. Simplicity is not inimical to patentability.

In re Oetiker, 977 F.2d 1443, 24 U.S.P.Q. 2d 1443 (Fed. Cir. 1992)

As in *Oetiker*, the present invention has been reconstructed with the benefit of hindsight. No skilled person would look to the wire sheath inserter arts for a solution to improved phacoemulsification surgery for removing cataracts. It is simply improper to use the present invention and cobble disparate prior art together to reconstruct Applicant's invention.

As the C.C.P.A. has stated:

In resolving the question of obviousness under 35 U.S.C. §103, we presume full knowledge by the inventor of all prior art in the field of his endeavor. However, with regard to prior art outside the field of his endeavor, we only presume knowledge from those arts reasonably pertinent to the particular problem with which the inventor was involved.

In re Wood, 599 F.2d 1032, 202 USPQ 171, 174 (C.C.P.A. 1979).

The Federal Circuit has further said

A reference is reasonably pertinent if . . . it is one which, because of the matter with which it deals, logically would have commanded itself to the inventor's attention in considering his problem. . . . If a referenced disclosure has the same purpose of the claimed invention, the reference relates to the same problem. . . . [I]t is directed to a different purpose, the inventor would accordingly have less motivation or occasion to consider it.

In re Clay, 966 F.2 656, 23 USPQ 2d 1058, 1060-61 (Fed. Cir. 1992).

In the present case, the field of endeavor of Zadno-Azizi is different from that of the present invention. Zadno-Azizi is directed to a sheath assembly for

introducing a wire or balloon into a valve assembly and ultimately into a blood vessel and the present invention is related to a phacoemulsification cannula. Therefore, as the C.C.P.A. and the Federal Circuit have stated, such a reference by Zadno-Azizi would not have been considered by one skilled in the art of ophthalmic phacoemulsification cannulas because the purpose of the present invention and the purpose of Zadno-Azizi are completely different.

The recent Supreme Court decision in *KSR International Co. v. Teleflex Inc. et al.*, 550 U.S. ____ (2007), does not effect of the above arguments and citations. KSR dealt with an obvious modification of an adjustable automotive foot pedal based on other automotive foot pedal prior art. No such similar situation exists in the present case. The present invention allows for greater transfer of ultrasonic displacement energy and operation at a higher vacuum rate with a lower flow rate than prior phacoemulsification needles. This advantage has nothing to do with the inserter sheath of Zadno-Azizi.

The Examiner reaches to find the structural elements of the claimed invention in cardiology and intravenous access - medical areas completely distinct from the instant application. The Zadno-Azizi reference deals with a balloon catheter for an angioplasty procedure in which the cited structure is wholly inserted into a Y-adapter 308, which in turn, is inserted into the blood vessel. The Eliasen reference deals with intravenous access, specifically the stabilization of an intravenous conduit for the administration of drugs into the blood stream. Neither of these references is within the knowledge of one skilled in the art of ophthalmic surgery or ultrasonic surgery.

The cited references also fall outside the analogous arts, as neither is pertinent to the problem faced and claimed by the inventor of the instant application. The instant invention has advantages in the transfer of ultrasonic displacement energy and operation at a higher vacuum rate with a lower flow rate. Neither the solution nor the benefit of the instant application is mentioned, contemplated, or even alluded to in the references cited by the Examiner. The Zadno-Azizi reference instead boasts increased protection to the interior of the blood vessels. The Eliasen reference discloses conduit stabilization for ease of use and reduces skin irritation/infection. Neither the solution nor the benefit of the instant application is mentioned, contemplated, or even alluded to in the references cited by the Examiner. Thus, the Zadno-Azizi and Eliasen references are not within an analogous art and are irrelevant to the immediate question of patentability.

Notwithstanding the relevance of the cited references, no motivation to combine the references is provided by the record, nor does it exist. The Examiner bases the combination of the fact that the Zadno-Azizi references indicated that other connections might be used. From this statement, the Examiner conclusively states that a threaded connection would be obvious to provide a secure connection. A general conclusion that increased security is always desirable is not a sufficient motivation to combine the cited references. The combination of the references unknown to one skilled in the art of ophthalmic or ultrasonic surgery is based on the impermissible use of the inventor's own

disclosure, not on permissible motivation. Thus, the combination of Zadno-Azizi and Eliasen references is improper.

The Examiner has given little or no weight to the functional language of the claims that was added to distinguish the present claimed invention from the cited art. Such a position by the Examiner is in complete opposition to long-standing law. Specifically, as stated by the C.C.P.A.:

We take the characterization "functional", as used by the Patent Office and argued by the Parties, to indicate nothing more than the fact that an attempt is being made to define something (in this case, a composition), by what it *does* rather than by what it *is* (as evidenced by specific structure or material, for example). In our view, there is nothing intrinsically wrong with the use of such a technique in drafting patent claims. Indeed, we have even recognized in the past the practical necessity for the use of functional language.

In re Swinehart, 439 F.2d 210, 169 USPQ 226, 228-29 (C.C.P.A. 1971). See also *In re Bisley*, 197 F.2d 355, 94 USPQ 80, 83 (C.C.P.A. 1952).

Therefore, the functional language of the present claims clearly distinguishes the present invention from the prior art, and should be given patentable weight and the pending claims allowed.

Simply put, no one skilled in the art of phacoemulsification or other ultrasonic surgery would look to the cited prior art for teaching or motivation, let alone come up with the claimed invention.

Independent claims 1, 5, and 9 have been amended to specifically refer to the needle and surgical instrument as a phacoemulsification needle and a phacoemulsification surgical instrument. This distinction clearly removes any similarity between the cited prior art and the claimed present invention. The

phacoemulsification cannula as claimed in the present invention is for use in extracting or aspirating cataract tissue from a patient's eye, not to introduce a foreign body into a human blood vessel, as Zadno-Azizi teaches.

The Examiner also asserts that the present claims use broad and functional language. Applicants assert that the language is not overly broad in that the claims limit the invention to a phacoemulsification cannula and specify that the larger diameter extends from the distal end toward the proximal end and that the transition to the smaller diameter is closer to the proximal end than to the distal end. Such an arrangement is not known in the ultrasonic arts and provides advantages over the known phacoemulsification cannulas.

For the reasons stated above, the claimed invention is patentable in light of the Zadno-Azizi and Eliasen references. These references are irrelevant to the obviousness inquiry concerning the instant application, because they exist outside of the knowledge of one skilled in the art of ophthalmic or ultrasonic surgery. Additionally, sufficient motivation to combine the cited references is not presented in the record, nor does one exist. The obviousness rejection of claims 1, 2, 5, 6, 9, and 10 should be reversed, and the instant application should be allowed to proceed to issuance.

Therefore, in view of the above arguments, it is respectfully submitted that the present invention is in condition for allowance, and such allowance is requested at an early date.

VIII. CLAIMS APPENDIX

1. **(Previously Amended)** A phacoemulsification cannula comprising:
a threaded hub for engagement with a phacoemulsification surgical instrument;
an elongated phacoemulsification needle having a proximal end attached to the
hub and a distal end; and
the phacoemulsification needle having a first and second inner diameter wherein
the first inner diameter is larger than the second inner diameter and
wherein a transition from the first inner diameter to the second
inner diameter is closer to the proximal end than to the distal
end and wherein the first inner diameter extends from the distal
end toward the proximal end, and wherein ultrasonic energy is transferred
from the surgical instrument to the needle during surgery.
2. **(Previously Amended)** The cannula of claim 1, wherein the transition includes
a radius.
3. **(Previously Canceled)** The needle of claim 1, wherein the transition includes a
conical surface connecting the first and second inner diameters.
4. **(Previously Canceled)** The needle of claim 1, wherein the transition includes at
least one additional inner diameter stepped between the first and second inner
diameters wherein the additional inner diameter is smaller than the first inner
diameter and larger than the second inner diameter.

5. **(Previously Presented)** A phacoemulsification needle comprising:
an elongated phacoemulsification needle having proximal and distal ends,
wherein the proximal end is structured for attachment to a
phacoemulsification surgical instrument; and
the needle having a first and a second inner diameter wherein the first inner
diameter is larger than the second inner diameter and wherein a transition
from the first inner diameter to the second inner diameter is closer to the
proximal end than to the distal end and wherein the first inner diameter
extends from the distal end toward the proximal end.
6. **(Original)** The needle of claim 5, wherein the transition includes a radius.
7. **(Previously Canceled)** The needle of claim 5, wherein the transition includes a
conical surface connecting the first and second inner diameters.
8. **(Previously Canceled)** The needle of claim 5, wherein the transition includes at
least one additional inner diameter stepped between the first and second inner
diameters wherein the additional inner diameter is small than the first inner
diameter and larger than the second inner diameter.

9. **(Previously Amended)** A phacoemulsification cannula comprising:
an elongated phacoemulsification needle having proximal and distal ends,
wherein the proximal end is structured for attachment to a
phacoemulsification surgical instrument;
a first bore within the cannula extending from the distal end toward the
proximal end;
a second bore within the cannula extending from the proximal end to the
first bore; and
wherein the second bore has a smaller diameter than the first bore and is
of sufficient length to provide a desired pressure drop during use
across the length of the second bore and wherein an intersection of
the first and second bores is nearer the proximal end than the distal
end.

10. **(Previously Amended)** The cannula of claim 9, wherein the transition includes
a radius.

11. **(Previously Canceled)** The needle of claim 9, wherein the transition includes
a conical surface connecting the first and second inner diameters.

12. **(Previously Canceled)** The needle of claim 9, wherein the transition includes at
least one additional inner diameter stepped between the first and second inner
diameters wherein the additional inner diameter is smaller than the first inner
diameter and larger than the second inner diameter.

IX. EVIDENCE APPENDIX

None

X. RELATED PROCEEDINGS APPENDIX

None

Respectfully submitted,



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DATE: July 13, 2007

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